

Notice of Allowability

Application No.

09/596,141

Examiner

Manjunath N. Rao, Ph.D.

Applicant(s)

LAWN ET AL.

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1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to to the paper filed on 2-21-04.
2. ☒ The allowed claim(s) is/are 1,8,10,12,14,16 and 18-20.
3. ☒ The drawings filed on 30 December 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Manjunath N. Rao, Ph.D.
Primary Examiner
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DETAILED ACTION

Claims 1, 8, 10, 12, 14, 16, 18-20 are currently pending and are present for examination.

Applicants' amendments and arguments filed on 2-21-04, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Specifically, Examiner has withdrawn all previous rejections in view of cancellation of all rejected claims by the applicants.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for SEQ ID NO:3 of this application.

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

EXAMINER'S AMENDMENT

Please amend the specification as follows.

Please replace the paragraph on page 89, lines 1-20 with the following amended paragraph.'

--Previous genetic linkage analysis mapped the TD gene to the 7-cM region of human chromosome 9q31 (Rust et al., Nat. Genet., 20, 96-98 (1998)). In addition, *in situ* hybridization analyses revealed that the ABCI gene was localized to the broader chromosomal interval 9q22 -

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9q31 (Luciani et al., Genomics, 21, 150-159 (1994)). Using PCR methods with the GeneBridge 4 panel of human/hampster radiation hybrids (Research Genetics, Inc., Huntsville, AL), human ABC1 was determined to be located between the markers W1-14706 and W1-4062, corresponding to the 7-cM region of human chromosome 9q31. DNA from 93 human/hampster hybrid cell lines was amplified by PCR using human ABC1-specific primers LF: CCTCTCATTACACAAAAACCAGAC (SEQ ID NO: 11) and LR: GCTTTCTTTCACCTTCTCATCCTG (SEQ ID NO: 12). Each line was scored as positive or negative for the human ABC1 amplification product and the mapping of ABC1 derived from analysis of this data was accomplished using the Whitehead Institute/MIT Center for Genome Research software, accessed via the internet (<http://carbon.wi.mit.edu:8000/cgi-bin/contig/rhmapper.pl>) (<http://carbon.wi.mit.edu:8000/cgi-bin/contig/rhmapper.pl>). These results were further confirmed by southern blot hybridization to human genomic/yeast artificial chromosome clones (Research Genetics, Inc.) from the equivalent interval. In addition, public database searching (GeneMap '98; National Center for Biotechnology Information) and radiation hybrid mapping eliminated the other significantly underexpressed genes in the microarray data from the location in the reported genetic interval. These complementary data demonstrate that the ABC1 gene is located on human chromosome 9q31 and further indicate that the ABC1 gene is associated with Tangier disease.--

Examiner has made the above informal examiner's amendment in order to cancel the embedded hyperlink and/or other form of browser-executable code in the specification. See MPEP § 608.01.

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Allowable Subject Matter

Claims 1, 8, 10, 12, 14, 16, 18-20 are allowed.

The following is an examiner's statement of reasons for allowance: Following a diligent search it was determined that the prior art neither teaches nor suggests an isolated polynucleotide having ABC1 promoter activity comprising SEQ ID NO:3 as claimed in claims 1, 8, 10, 12, 14, 16, 18-20 .

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of

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this application or proceeding should be directed to the receptionist whose telephone number is
571-272-1600.

A handwritten signature in black ink, appearing to read "Manjunath". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Manjunath N. Rao

May 5, 2004